

Food and Drug Administration
Center for Drug Evaluation and Research

SUMMARY MINUTES
ARTHRITIS ADVISORY COMMITTEE

May 6 & 7, 1997
Gaithersburg Hilton
620 Perry Parkway, Gaithersburg, MD

Members Present

Michelle Petri M.D., M.P.H., Chair
Steven B. Abramson, M.D.
Barbara C. Tilley, Ph.D.
Leona Malone, MSW
Frank Pucino, Jr., Pharm.D.
Daniel J. Lovell, M.D., M.P.H.
David Felson, M.D., M.P.H.
Lee Simon, M.D.
Harvinder Luthra, M.D.
Felix Fernandez-Madrid, M.D., Ph.D.

FDA Participants

Wiley A. Chambers, M.D.
Kent R. Johnson, M.D.
Christina L. Fang, M.D.
John E. Hyde, M.D., Ph.D.
James P. Witter, M.D., Ph.D.
Rudolph M. Widmark, M.D., Ph.D.
William D. Schwieterman, M.D.
Jeffrey N. Siegel, M.D.
Barbara G. Matthews, M.D.

Consultants

Guest Experts

Members Absent


Matthew Liang, M.D., M.P.H.


Executive Secretary

Kathleen R. Reedy

These summary minutes for the May 6 and 7, 1997 meeting of the Arthritis Advisory Committee were approved on 6/4/99.

I certify that I attended the May 6 and 7, 1997 meeting of the Arthritis Advisory Committee and that these minutes accurately reflect what transpired.


Kathleen R. Reedy,
Executive Secretary


Michelle A. Petri, M.D., M.P.H.
Chairperson

The Arthritis Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met at the Gaithersburg Holiday Inn 2 Montgomery Village Avenue, Gaithersburg, MD. on May 6 and 7, 1997 for an Annual Update of the Advisory Committee of the issues and drugs in IND, Phase 1 and 2 stages. This Annual Update alerts the Committee to the typics and products which might be brought for consideration of the Advisory Committee in the future.

The meeting was called to order at 8:30 am by Michelle Petri, M.D., M.P.H. Chairperson of the Arthritis Advisory Committee, and began with the introduction of those present at the discussion table. The meeting statement regarding conflict of interest was read by Kathleen Reedy, Executive Secretary, followed by welcoming comments by Wiley A. Chambers, M.D., Acting Director of the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products.

A video on ethics situations and resolution for Advisory Committee members was shown and discussed. Recent actions of the Division, NDA approvals and non-approvals, was presented by Wiley A. Chambers, M.D., Acting Director of the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products.

Products being reviewed in the Center for Biologics Evaluation and Research were presented by CBER staff. Products being reviewed in the CDER Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products were presented by medical officers on that staff.

The discussion ended at 4:30 pm on May 6, resumed at 8:30 am on May 7 and the meeting was adjourned at 12:00 m.